

Notice of Allowability

Application No.

09/284,100

Examiner

Elizabeth C. Kemmerer, Ph.D.

Applicant(s)

NARHI ET AL.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the response of 24 September 2003 and the interview of 31 October 2003.
2. ☒ The allowed claim(s) is/are 6-8, 10-22 and 25-29; renumbered as 2-10, 13-15, 18, 19, 12, 17, 1, 11, 16, 20 and 21, respectively.
3. ☒ The drawings filed on 07 April 1999 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____ | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Donald Zuhn on 31 October 2003.

The application has been amended as follows:

The following is a complete copy of the claims, including examiner's amendments to claims 17 and 19, and new claim 29:

1-5. (Canceled)

6. The KGF-2 protein according to Claim 25, wherein said amino acid sequence is nonglycosylated.

7. The KGF-2 protein according to Claim 25, wherein said amino acid sequence is glycosylated.

8. A chemical derivative comprising a water-soluble polymer conjugated to the KGF-2 protein according to Claim 25.

9. (Canceled)

10. A polynucleotide encoding the KGF-2 protein according to Claim 25.
11. A vector comprising a polynucleotide of Claim 10 operatively linked to an expression control sequence.
12. A prokaryotic or eukaryotic host cell containing a polynucleotide of Claim 10.
13. A method comprising culturing the host cell of Claim 12 in a suitable nutrient medium.
14. The method according to Claim 13, wherein said host cell is an *E. coli* cell.
15. The method according to Claim 13, wherein said host cell is selected from a baculovirus cell, COS cell or Chinese hamster ovary cell.
16. A method comprising the step of isolating a keratinocyte growth factor-2 (KGF-2) protein from a host cell containing a polynucleotide of Claim 10 cultured under conditions allowing the expression of the KGF-2 protein by said host cell.

17. (Twice Amended) The method according to Claim 16 comprising the step of conjugating the isolated KGF-2 protein to a water-soluble polymer to generate a compound capable of stimulating the production of epithelial cells.

18. A method comprising the steps of:

(a) culturing a prokaryotic or eukaryotic host cell containing a polynucleotide of Claim 10; and

(b) maintaining said host cell under conditions allowing the expression of a keratinocyte growth factor-2 (KGF-2) protein by said host cell.

19. (Thrice amended) A KGF-2 protein which is the recombinant expression product of a prokaryotic or eukaryotic host cell containing an exogenous polynucleotide of Claim 10.

20. A pharmaceutical composition comprising the KGF-2 protein according to Claim 25 in association with a pharmaceutically acceptable vehicle.

21. A pharmaceutical composition comprising a keratinocyte growth factor-2 (KGF-2) protein isolated in accordance with the method of Claim 26 in association with a pharmaceutically acceptable vehicle.

22. A pharmaceutical composition comprising a keratinocyte growth factor-2 (KGF-2) protein isolated in accordance with the method of Claim 27 in association with a pharmaceutically acceptable vehicle.

23-24. (Canceled)

25. A keratinocyte growth factor-2 (KGF-2) protein selected from the group consisting of:

(a) a KGF-2 protein consisting of residues 66 through 208 of the amino acid sequence set forth in SEQ ID NO: 2; and

(b) a KGF-2 protein consisting of residues 66 through 208 of the amino acid sequence set forth in SEQ ID NO: 2 and an N-terminal methionine.

26. The method of Claims 13, 14 or 15 further comprising isolating a keratinocyte growth factor-2 (KGF-2) protein from said cultured cells or said nutrient medium.

27. The method of Claim 18, further comprising after step (b) the following step (c):

(c) isolating the KGF-2 protein expressed by said host cell.

28. The KGF-2 protein according to Claim 25, wherein at least one domain of the constant region of the heavy chain of human immunoglobulin is fused to the C-terminal end of the KGF-2 protein.

29. A recombinant fusion protein comprising the KGF-2 protein of Claim 25 fused to a heterologous protein.

REASONS FOR ALLOWANCE

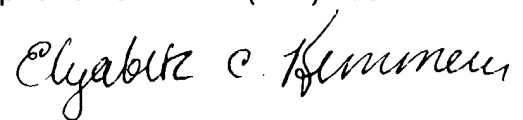
The following is an examiner's statement of reasons for allowance: The examiner's amendment was made to clarify the scope of the KGF-2 protein recited in claim 17, and to correct the improper multiple dependency in claim 19. Claim 29 was added at Applicant's request. The claim was deemed allowable by the examiner. Applicant's arguments were convincing such that all other objections and/or rejections are withdrawn.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (703) 308-2673. The examiner can normally be reached on Monday through Thursday, 6:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



ECK

ELIZABETH KEMMERER
PRIMARY EXAMINER